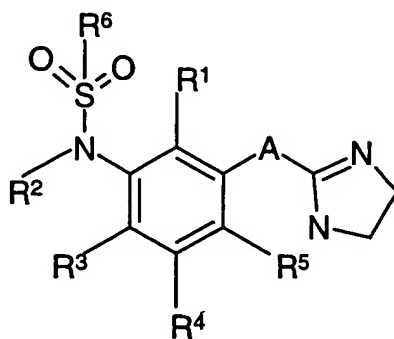


What is claimed is:

1. A stabilized oral pharmaceutical formulation comprising:
 - a) a nucleus formed by a core;
 - 5 b) a first layer that comprises a polymer coating sealing the core and optionally one or more hydrophobic excipients; and
 - c) a second layer coating the first layer, wherein said second layer comprises one or more labile pharmaceutically active compounds in one or more acceptable hydrophobic excipients.
- 10 2. The pharmaceutical formulation of Claim 1, wherein the polymer coating comprises an enteric polymer.
3. The pharmaceutical formulation of Claim 2, wherein the polymer coating comprises shellac or EudragitTM (L or S series).
4. The pharmaceutical formulation of Claim 3, wherein the one or more labile
15 pharmaceutically active compounds in the second layer are susceptible to hydrolytic degradation.
5. The pharmaceutical formulation of Claim 3, wherein the labile pharmaceutically active compound in the second layer is a compound comprising an imidazoline moiety.
- 20 6. The pharmaceutical formulation of Claim 5, wherein the labile pharmaceutically active compound in the second layer is a compound of Formula Ar-A-B, wherein Ar is a substituted aryl group, A is -NH-, -CH₂-, or -OCH₂-, and B is 2-imidazoline.

7. The pharmaceutical formulation of Claim 6, wherein the labile pharmaceutically active compound in the second layer is a compound of Formula I :



Formula I

5

wherein :

A is -NH-, -CH₂-, or -OCH₂-;

R¹, R³, R⁴, and R⁵ are each independently in each occurrence hydrogen, (C₁-C₆) alkyl, or halogen;

10 R⁶ is (C₁-C₆) alkyl;

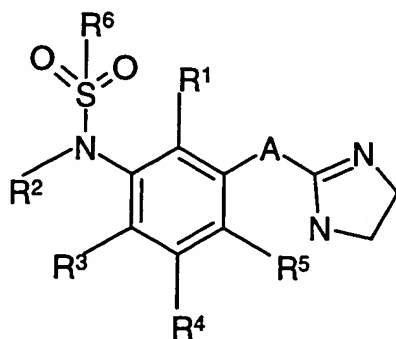
R² is hydrogen or (C₁-C₆) alkyl; or

R² and R³ taken together with the atoms to which they are attached may form a 5- or 6-membered ring;
or pharmaceutically acceptable salts thereof.

- 15 8. The pharmaceutical formulation of Claim 7, wherein the labile pharmaceutically active compound is a compound of Formula I, wherein A is -OCH₂-, R¹ and R⁶ are methyl, R³ is chloro, and R², R⁴ and R⁵ are hydrogen, named *N*-[6-chloro-3-(4,5-dihydro-1*H*-imidazol-2-ylmethoxy)-2-methyl-phenyl]-methanesulfonamide.

- 20 9. The pharmaceutically composition of Claim 1, wherein the labile pharmaceutically active compound in the second layer is *N*-[6-chloro-3-(4,5-dihydro-1*H*-imidazol-2-ylmethoxy)-2-methyl-phenyl]-methanesulfonamide.

10. The pharmaceutical formulation of Claim 1, further comprising a third layer coating the second layer, wherein the third layer is an enteric polymer.
11. The pharmaceutical formulation of Claim 7, further comprising a third layer coating the second layer, wherein the third layer is an enteric polymer.
- 5 12. The pharmaceutical formulation of Claim 8, further comprising a third layer coating the second layer, wherein the third layer is an enteric polymer.
13. A process for the formulation of a stable oral pharmaceutical formulation of Claim 1, which process comprises:
- 10 a) coating a core with a first layer sealing the core, wherein said first layer comprises an enteric polymer layer optionally comprising one or more hydrophobic excipients in a non-aqueous solvent.
- b) drying the first layer;
- c) coating the first layer with a second layer, wherein said second layer comprises one or more pharmaceutically active labile compounds, suspended
- 15 in one or more acceptable hydrophobic excipients;
- d) drying the second layer,
- e) optionally coating the second layer with a third layer, wherein said third layer comprises an enteric polymer in a non-aqueous solvent, and
- f) drying the third layer.
- 20 14. The process of Claim 13, wherein the labile pharmaceutically active compound is a compound of Formula I:



Formula I

wherein :

A is -NH-, -CH₂-, or -OCH₂-;

R¹, R³, R⁴, and R⁵ are each independently in each occurrence

5 hydrogen, (C₁-C₆) alkyl, or halogen;

R⁶ is (C₁-C₆) alkyl;

R² is hydrogen or (C₁-C₆) alkyl, or

R² and R³ taken together with the atoms to which they are attached
may form a 5- or 6-membered ring;

10 or pharmaceutically acceptable salts thereof.

15. The process of Claim 14, wherein the labile pharmaceutically active
compound is a compound of Formula I, wherein A is -OCH₂-, R¹ and R⁶ are
methyl, R³ is chloro, and R², R⁴ and R⁵ are hydrogen, named *N*-[6-chloro-3-
(4,5-dihydro-1*H*-imidazol-2-ylmethoxy)-2-methyl-phenyl]-
15 methanesulfonamide.
16. A method of treatment of urinary incontinence comprising administering a
stable oral pharmaceutical formulation according to Claim 7.
17. A method of treatment of urinary incontinence comprising administering a
stable oral pharmaceutical formulation according to Claim 8.
- 20 18. A method of treatment of urinary incontinence comprising administering a
stable oral pharmaceutical formulation according to Claim 9.
19. A method of treatment of urinary incontinence comprising administering a
stable oral pharmaceutical formulation according to Claim 11.
20. A method of treatment of urinary incontinence comprising administering a
25 stable oral pharmaceutical formulation according to Claim 12.
21. The method of treatment of Claim 16 comprising administering the stable oral
formulation in capsules or pellets.

22. The method of treatment of Claim 17 comprising administering the stable oral formulation in capsules or pellets.
23. The method of treatment of Claim 18 comprising administering the stable oral formulation in capsules or pellets.
- 5 24. The method of treatment of Claim 19 comprising administering the stable oral formulation in capsules or pellets.
25. The method of treatment of Claim 20 comprising administering the stable oral formulation in capsules or pellets.

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